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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

July 26, 2004

Ref: 04-DAL-WL-25

WARNING LETTER

Certified Mail
Return Receipt Requested

Alan D. Vander Horst, Owner
Sierra Dairy
P.O. Box 1547
Stephenville, Texas 76401

Dear Mr. Vander Horst:

A tissue residue report received by the Food and Drug Administration (FDA) from the United States Department of Agriculture (USDA) reported the presence of illegal drug residues in two cows that originated from your dairy. As a follow-up to USDA's finding, our investigators performed an inspection of your dairy operation located at Stephenville, Texas, on April 6, May 17, and June 1, 2004. The investigation confirmed that you offered two animals for sale for slaughter as human food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

On September 17, 2003 your dairy offered a dairy cow, identified with ear tag number [redacted] for slaughter as human food at [redacted] USDA Establishment Number [redacted] USDA analysis (Laboratory Report #436141) of tissue samples collected from that animal identified the presence of flunixin at 0.777 ppm in the liver. A tolerance of 0.125 ppm has been established for residues of flunixin meglumine in liver tissue of cattle. (Title 21, Code of Federal Regulations, Section 556.286).

Your dairy offered a second dairy cow for slaughter on February 20, 2004. The cow, identified with ear tag number [redacted] was also offered for slaughter as human food at [redacted] USDA analysis (Laboratory Report # 440588) of tissue samples collected from that animal identified the presence of flunixin at 0.287 ppm in the liver. A tolerance of 0.125 ppm has been established for residues of flunixin meglumine in liver tissue of cattle. (Title 21, Code of Federal Regulations, Section 556.286).

The presence of these drugs, at the reported levels, in the edible tissues of these animals, cause the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

A food is also adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions . . . whereby it may have been rendered injurious to health." Our investigation found that you hold animals under conditions which are so inadequate that medicated animals bearing potentially harmful drug residues may enter the food supply. You lack an adequate system for assuring that animals have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. You also lack an adequate system to document treatment administered to all cattle on your dairy. For example, you told our investigators that your firm's medication records system is only set up to track treatment of lactating cattle. Foods from animals held under such conditions are adulterated.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act. It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure, and/or injunction.

You should notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If the corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the Food and Drug Administration, Attention: Sherrie L. Krolczyk, Recall and Emergency Coordinator.

Sincerely yours,

Michael A. Chappell
Dallas District Director

MAC:SLK